



**BILLING CODE 3410-DM-P**

**DEPARTMENT OF AGRICULTURE**

**Food Safety and Inspection Service**

**9 CFR Part 557**

**[Docket No. FSIS-2018-0030]**

**RIN [0583-AD73]**

**Eligibility of the People's Republic of China to Export Siluriformes Fish and Fish Products to the United States**

**AGENCY:** Food Safety and Inspection Service, USDA.

**ACTION:** Proposed rule.

**SUMMARY:** The Food Safety and Inspection Service (FSIS) is proposing to amend the Siluriformes fish inspection regulations to list the People's Republic of China (PRC) as a country eligible to export Siluriformes fish and fish products to the United States. FSIS is proposing this action because the Agency has reviewed the PRC's laws, regulations, and inspection system as implemented and has determined that the PRC's Siluriformes fish inspection system is equivalent to the system that the United States has established under the Federal Meat Inspection Act (FMIA) and its implementing regulations.

Under this proposal, only raw Siluriformes fish and fish products produced in certified PRC establishments would be eligible for export to the United States. All such products

would continue to be subject to re-inspection at United States points-of-entry by FSIS inspectors.

**DATES:** Submit comments on or before [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

**ADDRESSES:** FSIS invites interested persons to submit comments on the proposed rule. Comments may be submitted by one of the following methods:

- Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or to attach a file for lengthier comments. Go to <http://www.regulations.gov>. Follow the on-line instructions at that site for submitting comments.

- Mail, including CD-ROMs, etc.: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Room 6065, Washington, DC 20250-3700.

- Hand- or courier-delivered submittals: Deliver to 1400 Independence Avenue SW, Room 6065, Washington, DC 20250-3700.

*Instructions:* All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2018-0030. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

*Docket:* For access to background documents or comments received, call (202)720-5627 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW, Room 6065, Washington, DC 20250-3700.

**FOR FURTHER INFORMATION CONTACT:** Roberta Wagner, Assistant Administrator, Office of Policy and Program Development; Telephone: (202) 205-0495.

**SUPPLEMENTARY INFORMATION:**

**Background**

FSIS is proposing to amend its regulations at 9 CFR 557.2(b)(1) to add the PRC as a country eligible to export Siluriformes fish and fish products to the United States (for convenience, in this proposed rule, "Siluriformes fish and fish products" will be shortened to "Siluriformes fish"). Although the PRC has been allowed to export these products to the United States under the conditions described below, the PRC is not currently listed in the Code of Federal Regulations (CFR) as eligible to export Siluriformes fish to the United States.

Transitional Period

On December 2, 2015, FSIS published the final rule, "Mandatory Inspection of Fish of the Order Siluriformes and Products Derived from Such Fish" (80 FR 75590). The final rule established a mandatory FSIS inspection system for fish of the order Siluriformes and products derived from these fish. The

final regulations implemented the provisions of the 2008 and 2014 Farm Bills, which amended the FMIA, mandating FSIS inspection of Siluriformes fish.

The final rule provided an 18-month period, from March 1, 2016, to September 1, 2017, for both the U.S. domestic Siluriformes fish industry and international trading partners to transition from the regulatory requirements of the U.S. Food and Drug Administration (FDA), the agency formerly responsible for regulatory oversight of Siluriformes fish, to the regulatory requirements of FSIS. By March 1, 2016, FSIS required foreign countries to submit written documentation identifying a list of establishments that had been exporting and would continue exporting Siluriformes fish to the United States. In addition, by March 1, 2016, FSIS required foreign countries to submit written documentation to demonstrate that they had laws or other legal measures in place that provide authority to regulate the growing and processing of fish for human food, and to assure compliance with FDA's good manufacturing practices, Hazard Analysis and Critical Control Point (HACCP) requirements, sanitation control procedures, and other regulatory requirements in 21 CFR part 123, *Fish and Fishery Products*.

FSIS recognized the foreign countries' initial documentation until the end of the transition period on September 1, 2017. Foreign countries that wished to continue

exporting after September 1, 2017, were required to submit documentation substantiating the equivalence of their Siluriformes fish inspection system to that of the United States. Foreign countries that submitted complete equivalence documentation by September 1, 2017, were permitted to continue exporting Siluriformes fish until such time that FSIS determines if their Siluriformes fish inspection systems are equivalent to the U.S. system.

The PRC submitted its initial documentation in March 2017, which allowed it to continue exporting Siluriformes fish during the transitional period. In August 2017, the PRC submitted a Self-Reporting Tool (SRT), the questionnaire that FSIS uses to assess the equivalence of a foreign country's food safety inspection system.

FSIS stated in the final rule that, during the transitional period, it would reinspect imported Siluriformes fish and test for species identification and residues at least on a quarterly basis for each foreign establishment that exported Siluriformes fish to the U.S. (80 FR 75608). FSIS conducted random and targeted sampling and testing of imported Siluriformes fish during the transitional period, and on August 2, 2017, began reinspecting all shipments of Siluriformes fish, with random sampling for species and residue testing. During the testing, FSIS found residue violations in shipments of

Siluriformes fish exported from the PRC. When imported product fails FSIS testing, the product is refused entry and the designated competent authority of the foreign government's inspection system is notified and further shipments of product from the foreign establishment are placed under either an increased or intensified level of sampling. FSIS notified the General Administration of Customs People's Republic of China (GACC), the PRC's central competent authority for food inspection, of the residue violations. In response, GACC completed investigations to determine the cause of the violations and implemented corrective actions as necessary.

#### **Statutory and Regulatory Basis for Proposed Action**

Siluriformes fish are an amenable species under the FMIA (21 U.S.C. 601(w)(2)). The FMIA prohibits importation into the United States of adulterated or misbranded meat and meat food products (21 U.S.C. 620). Under the FMIA and its implementing regulations, Siluriformes fish imported into the United States must be from foreign countries that maintain an inspection system that ensures compliance with requirements equivalent to all the inspection, sanitary, quality, species verification, and residue standards, and all other provisions of the FMIA which are applied to official establishments in the United States. The regulatory requirements for foreign countries to become eligible to export Siluriformes fish to the United States are provided in

9 CFR 557.2, which cross-references 9 CFR 327.2, the regulations for the import of other products also subject to the FMIA. As noted above, FSIS has allowed the PRC to continue shipping Siluriformes fish while FSIS made the determination concerning whether the country's inspection system is equivalent to that of FSIS.

Section 557.2(a) (cross-referencing 9 CFR 327.2(a)(2)(i), (a)(2)(i), (a)(2)(ii)(C)-(I), (a)(2)(iii)-(iv), and (a)(3)), requires a foreign country's inspection system be authorized by legal authority that imposes requirements equivalent to those of the United States, specifically with respect to: (1) official controls by the national government over establishment construction, facilities, and equipment; (2) direct official supervision of the preparation of product to assure that product is not adulterated or misbranded; (3) separation of establishment operations for product certified for export from product that is not certified; (4) requirements for sanitation at certified establishments and for sanitary handling of product; (5) official controls over condemned materials; (6) a HACCP system; and (7) any other requirements found in the FMIA and its implementing regulations.

In addition to a foreign country's legal authority and regulatory requirements, the inspection program itself must achieve a level of public health protection equivalent to that

achieved by the U.S. program. Specifically, the inspection program organized and administered by the national government must impose requirements equivalent to those of the United States with respect to: (1) organizational structure and staffing, so as to ensure uniform enforcement of the requisite laws and regulations in all certified establishments; (2) ultimate control and supervision by the national government over the official activities of employees or licensees; (3) competent, qualified inspectors; (4) enforcement and certification; (5) administrative and technical support; (6) inspection, sanitation, quality, species verification, and residue standards; and (7) any other inspection requirements required by the regulations in Subchapter F - Mandatory Inspection of Fish of the Order Siluriformes and Products of Such Fish, which cross-references 9 CFR 327.2(a)(2)(i)).

The foreign country's inspection system must ensure that establishments preparing Siluriformes fish for export to the United States comply with requirements equivalent to those of the FMIA and the regulations promulgated thereunder. The foreign country certifies the establishments as having met the required standards and notifies FSIS about establishments that are certified or removed from certification.

As discussed above, a foreign country's inspection system must be evaluated by FSIS to determine its eligibility to export

Siluriformes fish to the United States. This evaluation consists of two processes: a document review and an on-site review. The document review is an evaluation of the laws, regulations, and other written materials used by the country to affect its inspection program. FSIS requests that countries provide information about their inspection systems through the SRT. The SRT can be found on the FSIS web site at *2016 Siluriformes SRT*. The SRT is a standardized questionnaire that FSIS provides to foreign governments to gather information that characterizes foreign inspection systems. Through the SRT, FSIS collects information on practices and procedures in six areas, known as equivalence components: (1) Government Oversight (e.g., Organization and Administration), (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling), (3) Government Sanitation, (4) Government HACCP Systems, (5) Government Chemical Residue Testing Programs, and (6) Government Microbiological Testing Programs. FSIS evaluates the information submitted to verify that the six equivalence components are addressed satisfactorily with respect to standards, activities, resources, and enforcement. If the document review is satisfactory, an on-site audit is scheduled using a multi-disciplinary team to evaluate all aspects of the country's inspection program. This comprehensive equivalence

determination process is described more fully on the FSIS Web site at

<http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/equivalence/equivalence-process-overview>.

Under the regulations, foreign countries must be listed in the CFR as eligible to export Siluriformes fish to the United States. FSIS engages in rulemaking to list a country as eligible to export Siluriformes fish to the United States in the regulations at 9 CFR 557.26(b)(1). Once listed, the eligible country is required to certify that establishments meet the requirements to export Siluriformes fish to the United States and to ensure that products from these establishments are safe, wholesome, and not misbranded. To verify that products imported into the United States are safe, wholesome, and properly labeled and packaged, FSIS conducts 100 percent re-inspection of those products at points-of-entry before they enter the U.S. commerce.

#### **Evaluation of the PRC Siluriformes Fish Inspection System**

In March 2017, the PRC submitted an initial equivalence application and requested that FSIS conduct a review of PRC's Siluriformes fish inspection system to establish eligibility to export Siluriformes fish to the United States. FSIS conducted a document review of the PRC's Siluriformes fish inspection system to determine whether that system was equivalent to that of the

United States. FSIS concluded, based on review of the submitted documentation, that the PRC's laws, regulations, control programs, and procedures were equivalent to those of the United States.

Accordingly, FSIS proceeded with an on-site audit of the PRC's Siluriformes fish inspection system in May 2018, to verify whether the PRC's GACC effectively implemented a Siluriformes fish inspection system equivalent to that of the United States. The PRC currently only exports raw Siluriformes fish. FSIS auditors visited six of the 14 slaughter and raw processing establishments currently certified as eligible by the GACC to export Siluriformes fish and fish products to the United States and two pre-harvesting farms that provide raw fish to two of the audited establishments.

The audit did not identify any deficiencies that represented an immediate threat to public health. The audit did identify deficiencies that could lead to product contamination if not adequately addressed. The auditors identified deficiencies regarding government oversight. Specifically, in one audited provincial office, the GACC inspection personnel did not document all noncompliances identified during their verification activities. The auditors also identified deficiencies involving sanitation. Specifically, in one establishment, rusted pipes and loose silicone were observed on the overhead structures on the

ceiling over exposed products in the production areas. In another establishment, beaded condensate was observed over exposed product in several production areas.

In addition, the auditors identified deficiencies regarding HACCP. Specifically, in all six establishments audited, establishments' ongoing verification activities did not include direct observations of monitoring activities. In five out of the six establishments audited, establishment verification records did not include the times or results of the verification activities. In four of the six establishments audited, corrective action records did not include all four parts of the corrective actions to be followed in response to a deviation from a critical limit. Lastly, in two establishments out of the six audited, monitoring records did not include the initials or signature of the establishment employee making the entry.

In summary, in the audit exit meeting, GACC committed to address the findings as presented. FSIS auditors will perform a follow-up audit in November 2018 to verify implementation of the PRC's corrective action plan and ensure that all outstanding issues have been resolved. Because none of these outstanding issues present an immediate public health threat, FSIS is proposing to list the PRC as eligible to ship Siluriformes fish to the United States. FSIS will post the follow-up audit on its

web site, will request comments on the follow up audit, and will consider those comments in developing the final rule.

The full report on the PRC's Siluriformes fish inspection system can be found on the FSIS Web site at <http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports/foreign-audit-reports>.

At this time, the PRC intends to certify fourteen establishments as eligible to export product to the U.S. The establishments intend to export raw Siluriformes fish. Should this rule become final, the government of the PRC must certify to FSIS those establishments that wish to export Siluriformes fish to the United States and that operate in accordance with requirements equivalent to that of the United States (9 CFR 557.2(a)). FSIS will verify that the establishments certified by the PRC's government are meeting the United States requirements through verification audits of the PRC's Siluriformes fish inspection system.

Although a foreign country may be listed in FSIS regulations as eligible to export Siluriformes fish to the United States, the exporting country's products must be found to comply with all other applicable requirements of the United States. Accordingly, Siluriformes fish exported from the PRC will continue to be subject to re-inspection at U.S. points-of-

entry for, but not limited to, transportation damage, product and container defects, labeling, proper certification, general condition, and accurate count. In addition, FSIS is, and will continue, to conduct other types of re-inspection activities, such as taking product samples for laboratory analysis for the detection of drug and chemical residues, pathogens, species, and product composition for a subset of PRC's Siluriformes fish imported into the United States. Products that pass re-inspection will be stamped with the official mark of inspection and allowed to enter U.S. commerce. If they do not meet U.S. requirements, they will be refused entry and within 45 days must be exported to the country of origin, destroyed, or converted to animal food (subject to approval of FDA), depending on the violation. The import re-inspection activities can be found on the FSIS Web site at

[http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/phis-import-component/phis-implementation-letter-to-importers/ct\\_index](http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/phis-import-component/phis-implementation-letter-to-importers/ct_index).

### **Executive Orders 12866 and 13563, and the Regulatory Flexibility Act**

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic,

environmental, public health and safety effects, distributive impacts, and equity). Executive Order (E.O.) 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This proposed rule has been designated as a “non-significant” regulatory action under section 3(f) of E.O. 12866. Accordingly, the rule has not been reviewed by the Office of Management and Budget under E.O. 12866.

#### **Expected Costs of the Proposed Rule**

As shown in Table 1, the PRC accounted for approximately 10 percent of Siluriformes fish imports and represented only 3.6 to 5.2 percent of Siluriformes fish consumption in the United States. The proposed rule is not expected to change the PRC’s market share. If finalized, the proposed rule is not expected to have any cost to industry or consumers, because the proposed rule would maintain historical trade.

Table 1. Summary of Siluriformes Sales

	2013	2014	2015	2016	2017	5 Year Average
	<b>Millions of Dollars</b>					
<b>Total U.S. Imports<sup>1</sup></b>	\$363.42	\$346.66	\$351.13	\$405.61	\$381.89	\$369.74
<b>Total U.S. Domestic Production<sup>2</sup></b>	\$356.73	\$351.94	\$363.61	\$385.99	\$379.71	\$367.60
<b>Total U.S. Exports<sup>1</sup></b>	\$4.69	\$4.00	\$4.95	\$4.80	\$6.18	\$4.92
<b>U.S. Consumption of U.S. Production</b>	98.7%	98.9%	98.6%	98.8%	98.4%	98.7%
<b>Total U.S. Consumption<sup>3</sup></b>	\$715.46	\$694.60	\$709.79	\$786.80	\$755.43	\$732.41
<b>Total U.S. Imports from the PRC<sup>1</sup></b>	\$25.97	\$36.19	\$32.06	\$37.46	\$38.35	\$34.01
<b>The PRC as % of U.S. Imports</b>	7.1%	10.4%	9.1%	9.2%	10.0%	9.2%
<b>The PRC as % of U.S. Domestic Production</b>	7.3%	10.3%	8.8%	9.7%	10.1%	9.3%
<b>The PRC as % of U.S. Consumption</b>	<b>3.6%</b>	<b>5.2%</b>	<b>4.5%</b>	<b>4.8%</b>	<b>5.1%</b>	<b>4.6%</b>

Data Source: U.S. Census Bureau Trade Data

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<sup>1</sup>Import and Export Data Accessed from USDA Foreign Agricultural Service: Global Agricultural Trade System:

<https://apps.fas.usda.gov/gats/default.aspx>

<sup>2</sup>U.S. Production Data Accessed from USDA National Agricultural Statistics Service: Quick Stats:

<https://quickstats.nass.usda.gov/>

<sup>3</sup>U.S. Consumption data is assumed to equal Imports + Domestic Production - Exports

### **Expected Benefits of the Proposed Rule**

Should this proposed rule become final, the Siluriformes fish trade between the United States and the PRC, and its associated benefits, would be maintained. As shown in Table 2, the United States is the PRC's largest foreign customer of Siluriformes fish, purchasing 63 to 71 percent of their total exports from 2015 to 2017. As shown in Table 1, the U.S. consumes 98.7 percent of all Siluriformes fish that it produces. U.S. production meets half of U.S. total demand. Maintaining current trade flows would help keep consumer prices for Siluriformes fish affordable and meet the large U.S. demand for these products. Additionally, the PRC provides several species of Siluriformes fish that are not produced domestically, allowing for greater product diversity and consumer choice.

Table 2. Chinese Siluriformes Export Market Share by Country

Partner Country*	USD in millions			% Share		
	2015	2016	2017	2015	2016	2017
World	\$49.30	\$50.40	\$41.30	100%	100%	100%
United States	\$30.87	\$35.92	\$27.32	63%	71%	66%
Cote d Ivoire	\$0.61	\$5.74	\$4.14	1%	11%	10%
Hong Kong	\$7.24	\$7.05	\$2.40	15%	14%	6%
Congo, Dem. Rep.	\$2.30	\$1.92	\$2.07	5%	4%	5%
Congo	\$2.26	\$0.75	\$1.33	5%	1%	3%
Ghana	\$0.04	\$0.14	\$1.04	0%	0%	3%
Cameroon	\$3.62	\$0.09	\$0.57	7%	0%	1%
Korea, South	\$0.64	\$0.36	\$0.40	1%	1%	1%
Thailand	\$0.07	\$0.05	\$0.37	0%	0%	1%
Angola	\$1.03	\$0.12	\$0.12	2%	0%	0%
Mali	\$0.0	\$0.32	\$0.12	0%	1%	0%
Zambia	\$0.33	\$0.31	\$0.04	1%	1%	0%

Data Source: Global Trade Atlas - International Import and Export Commodity Trade Data (Numbers reported by Chinese Customs)

[http://www.gtis.com/gta\\_3d/scripts/commodity.cfm](http://www.gtis.com/gta_3d/scripts/commodity.cfm)

### Regulatory Flexibility Act Assessment

The FSIS Administrator has made a preliminary determination that this proposed rule would not have a significant economic

impact on a substantial number of small entities in the United States, as defined by the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The expected trade volume is expected to remain within historical bounds, with little or no effect on U.S. establishments, regardless of size.

#### **Executive Order 13771**

Consistent with E.O. 13771 (82 FR 9339, February 3, 2017), this proposed rule facilitates regulatory cooperation with foreign governments. Therefore, if finalized as proposed, this rule is expected to be an E.O. 13771 deregulatory action.

#### **Paperwork Reduction Act**

No new paperwork requirements are associated with this proposed rule. Foreign countries wanting to export Siluriformes fish to the United States are required to provide information to FSIS certifying that their inspection system provides standards equivalent to those of the United States, and that the legal authority for the system and their implementing regulations are equivalent to those of the United States. FSIS provided the PRC with a questionnaire, referred to as the SRT, asking for detailed information about the country's inspection practices and procedures to assist the country in organizing its materials. This information collection was approved under OMB

number 0583-0153. The proposed rule contains no other paperwork requirements.

### **E-Government Act**

FSIS and the U.S. Department of Agriculture (USDA) are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601, et seq.) by, among other things, promoting the use of the Internet and other information technologies and providing increased opportunities for citizen access to Government information and services, and for other purposes.

### **Additional Public Notification**

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication and officially notify the World Trade Organization's Committee on Sanitary and Phytosanitary Measures (WTO/SPS Committee) in Geneva, Switzerland, of this proposal on-line through the FSIS Web page located at:

<http://www.fsis.usda.gov/federal-register>.

FSIS also will make copies of this publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. Constituent Updates are available on the FSIS Web page. Through the Web page, FSIS is able to

provide information to a much broader, more diverse audience. In addition, FSIS offers an e-mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: <http://www.fsis.usda.gov/subscribe>. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves and have the option to password protect their accounts.

#### **USDA Non-Discrimination Statement**

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Send your completed complaint form or letter to USDA by mail, fax, or email:

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Director, Office of Adjudication  
1400 Independence Avenue, SW  
Washington, DC 20250-9410

Fax: (202) 690-7442

E-mail: [program.intake@usda.gov](mailto:program.intake@usda.gov)

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.), should contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

#### **List of Subjects in 9 CFR Part 557**

Imported products.

For the reasons set out in the preamble, FSIS is proposing to amend 9 CFR part 557 as follows:

#### **PART 557—IMPORTATION**

1. The authority citation for part 557 continues to read as follows:

Authority: 21 U.S.C. 601-602, 606-622, 624-695; 7 CFR 2.7, 2.18, 2.53.

2. In § 557.2, revise paragraph (b)(1) to read as follows:  
§ 557.2 Eligibility of foreign countries for importation of fish and fish products into the United States.

\* \* \* \* \*

(b)(1) It has been determined that fish and fish products from the following countries covered by foreign inspection certificates of the country of origin as required by § 557.4, are eligible under the regulations in this subchapter for entry into the United States after inspection and marking as required by the applicable provisions of this part:

Peoples Republic of China

\* \* \* \* \*

Paul Kiecker,

*Acting Administrator.*

[FR Doc. 2018-20379 Filed: 9/14/2018 4:15 pm; Publication Date: 9/19/2018]